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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
OSTRUP, CLINTON T	

ART UNIT	PAPER NUMBER
3771	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,373	SHEIMAN, VLADIMIR	
	Examiner	Art Unit	
	CLINTON OSTRUP	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18,19,21-32,34,35 and 39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,19,21-32,34,35 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 November 2009* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to Applicant's amendment filed November 10, 2009. As directed by the amendment, claims 18, 22-24 and 34 have been amended and claim 39 has been added. Claims 1-17, 20, 33 and 36-28 are cancelled. Thus, claims 18-19, 21-32, 34-35, and 39 are pending in this application.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the features described at page 6, line 14 - page 7, line 2 and page 12, line 4 - page 10, line 11 as described in the specification. Figures 5-11 are described in the specification, but applicant has only presented figures 1-4 and has deleted figures 5-11 from the application. Applicant's attention is drawn to 37 CFR 1.84 Standards for drawings.

3. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each

drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 18-19, 21-32, 34-35, and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is indefinite because the metes and bounds of what constitutes "an aerosol tube positioned **about at least a** portion of the tubular energy transmitter" are unclear. Emphasis added.

Any remaining claims are rejected as depending from a rejected base claim.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 18-19, 21-32, 34-35, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over KHMELEV et al (RU 2070062 C1), based on the English translation

provided by The McElroy Translation Company for the United States Patent and Trademark Office (PTO 09-2827), herein referred to as KHMELEV and further in view of Avrahami (4,961,885).

KHMELEV discloses nebulizer (figure) comprising: a container (7) adapted to contain a liquid (8) to be nebulized; a tubular energy transmitter (17) proximate and spaced from the container (7); and an aerosol tube (18) positioned about at least a portion of the tubular energy transmitter (17); an energy source (2, 3, 4) being operatively coupled to the container (7 is operably coupled to 2, 3, 4 as shown in the figure) for nebulization of the liquid (7) and being configured for transmission of energy to a focal point (20) of the liquid proximate said one end of the tubular energy transmitter (17) whereby said liquid is forced toward an opposite end of the tubular energy transmitter (shown by arrows) and nebulized within the aerosol tube (18).

Although KHMELEV discloses a tubular energy transmitter (17) proximate and spaced from the container (7) as well as a cylindrical shaped container immersed in a fluid, KHMELEV lacks the tubular energy transmitter being immersed in the fluid.

Avrahami teaches an ultrasonic transducer that has a container for liquid to be nebulized and a liquid supply tube (20) which is immersed in the liquid in the container. See: 1-3.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the tubular energy transmitter (17 of KHMELEV) to be submerged in the liquid to be nebulizer in order to form a feed tube that deliver the

liquid to the nebulizer focal point (20 of KHMELEV) thereby eliminating the need for a separate liquid containing reservoir and container.

Regarding claim 19, KHMELEV teaches the energy source (2, 3, and 4) is positioned below the container (7).

Regarding claim 21, the tubular energy transmitter (20 of Avrahami) of the combined references is positioned so that said one end is proximate the bottom of the container. See: figure 1 of Avrahami.

Regarding claim 22, the combined references teach a tubular energy transmitter (20 of Avrahami) that vibrates at a frequency (via 2, 3, 4 of KHMELEV) for forming an aerosol proximate the opposite end of the energy transmitter (See: the figure with arrows showing aerosol being delivered in KHMELEV).

Regarding claim 23, the combined references have an aerosol tube (18 of KHMELEV) with a cross sectional area such that the positive pressure of the aerosol within the aerosol tube induces a pressure drop along the aerosol tube which propels the aerosol through the aerosol tube. See: figure of KHMELEV.

Regarding claim 24, the combined dereferences teach the internal diameter of the aerosol tube (18 of KHMELEV) is greater than an internal diameter of the tubular energy transmitter (20 of Avrahami) at the opposite end of the tubular energy transmitter.

Regarding claim 25, the aerosol tube (18 of KHMELEV) of the combined references is positioned so that it is substantially coaxial with the tubular energy transmitter (20 of Avrahami).

Regarding claim 26, the nebulizer of the combined references has an aerosol tube (18 of KHMELEV) that is connected to the opposite end of the tubular energy transmitter (20 of Avrahami).

Regarding claim 27, the device of the combined reference has an energy source (2, 3, and 4 of KHMELEV) that vibrates the liquid proximate the opposite end of the tubular energy transmitter (20 of Avrahami).

Regarding claim 30, the device of the combined references uses an energy source that comprises an ultrasonic transducer (2, 3, and 4) for transmission of ultrasonic radiation energy.

Regarding claim 31, the device of the combined references, uses an ultrasonic transducer (2, 3, 4) that has a concave shaped surface. See figure of KHMELEV.

Regarding claim 32, the ultrasonic transducer (2, 3, and 4 of KHMELEV) of the combined references is arranged to transmit ultrasonic energy to a focal region (20 of KHMELEV) of the liquid.

Regarding claim 34, the internal diameter of the tubular energy transmitter (20 of Avrahami) is substantially equal to a diameter of the focal region (20 of KHMELEV).

Regarding claim 35, it is the examiner's position that the tube forming the tubular energy transmitter (20 of Avrahami) inherently has a higher acoustic impedance than the liquid.

8. Claims 28-29 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over KHMELEV et al (RU 2070062 C1), based on the English translation provided by The McElroy Translation Company for the United States Patent and Trademark Office

(PTO 09-2827), herein referred to as KHMELEV in view of Avrahami (4,961,885), as applied to claims 18 and 23 above, and further in view of Sheiman (WO 99/42145 A1).

The combined references teach all the limitations of claim 28, except that the aerosol tube opens at its upper end into an expansion chamber which in turn communicates with an outlet duct (36).

Sheiman teaches an aerosol tube (32, 38) which opens at its upper end (32) into an expansion chamber (formed inside 32) which in turn communicates with an outlet duct (36).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the ultrasonic nebulization device disclosed by the combined references by placing an additional energy transmitter around the tube, as taught by Sheiman, in order to increase the kinetic energy of the atomized particles thereby allowing for smaller particle sized and better lung absorption of the particles.

Regarding claim 29, Sheiman teaches the expansion chamber (inside 32) is adapted (via 36 & 40) to re-circulate larger drops of the liquid back into the container (22).

Regarding claim 39, Sheiman discloses a partition wall (wall of 16) located to one side of the expansion chamber (28) to separate the outlet duct (42) from the tubular energy transmitter (20 of Avrahami).

Response to Arguments

9. Applicant's arguments with respect to claims 18-19, 21-32, 34-35, and 39 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771